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| D:\nda\2016\memo\nda logo.jpg | **National Drug Authority**  Plot No. 46 - 48 Lumumba Avenue,  P.O. Box 23096, Kampala, Uganda.  email: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug); website: [www.nda.or.ug](http://www.nda.or.ug) Tel: +256-414-255665, +256-414-347391/2 |  |
| 5. Format for Labelling EctoparasiticideTrial Products | | |

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*Outer/carton labels & Unit Pack*

**4.1** The following information shall be presented on the labeling of the product for trial:

|  |  |  |
| --- | --- | --- |
| *Parameters* | *Outer/carton labels* | *Unit Pack* |
| Study No. or Protocol | ? | ? |
| Group code | ? | ? |
| Product name or code | ? | ? |
| Dosage form | ?\*\* | ?\*\* |
| Name of active substance | ?\*\* | ?\*\* |
| Strength of active substance | ?\*\* | ?\*\* |
| Dilution for different species | ? | ? |
| Batch number | ?\*\* | ?\*\* |
| Manufacturing date or retest date | ? | ? |
| Expiry date | ? | ? |
| For Trial Use Only | ? | ? |
| Name and address of manufacturer or final release or product owner (corporate address)or sponsor | ?\*\*\* | ?\*\*\* |
| Route of administration | ? | ? |
| Storage conditions | ? | ? |
| Pack sizes (unit/Vol) | ? | ? |

\*\* Where applicable

\*\*\* With letter of authorization

If the product is supplied without an outer carton, the information that is required on the outer carton should be stated on the inner carton.